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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,754	02/10/2006	Akinori Arimura	2006-0134A	7713

513 7590 06/19/2008

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EXAMINER	
RICCI, CRAIG D	

ART UNIT	PAPER NUMBER
4161	

MAIL DATE	DELIVERY MODE
06/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,754	ARIMURA, AKINORI	
	Examiner	Art Unit	
	CRAIG RICCI	4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *1-6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/10/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 7 and 8 are currently pending and the subject of this Office Action. Claims 1-6 are withdrawn. This is the first Office Action on the merits of the claims.

Information Disclosure Statement

2. All references have been considered except Japan Patent No. 10-508870 which is not in English and does not contain an English abstract.

Priority

3. The earliest effective filing date afforded the instantly claimed invention has been determined to be 08/16/2004 as to claims 7 and 8. Acknowledgment is made of Applicant's claim for foreign priority pursuant to 35 U.S.C. 119(a) and 365(b) based on a prior application filed in Japan on 08/18/2003. The certified copy has been filed in parent Application No. PCT/JP04/011745, filed on 08/16/2004. (

Election/Restrictions

4. Applicant's election of Group IV in the reply filed on 5/14/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

5. Claims 1-6 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/14/2008.

6. The requirement is thus deemed proper and is therefore made FINAL.

7. The elected species read upon claims 7 and 8.

Claim Rejections - 35 USC § 112 second paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 7 is rejected under 35 U.S.C. 112 second paragraph for the following reasons: instant claim 7 provides for the "Use of a compound represented by the formula (II) in claim 3..." However, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

10. Claim 8 is rejected under 35 U.S.C. 112 second paragraph for the following reasons: instant claim 8 is drawn to "a method for preventing and/or treating a mammal, including a human, to alleviate" recited effects (claim 8). As drafted, the claim thus encompasses a method for preventing a mammal to alleviate the recited effects, which is nonsensical. Accordingly, as drafted, claim 8 is vague and indefinite.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 7 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper

definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by *Tada et al* (US 6,977,266).

13. As discussed above, instant claim 8 as drafted is vague and indefinite. However, as interpreted by Examiner, the claim appears to be drawn to methods of treating pathological effects that include respiratory inflammation and irritability using cannabinoid receptor antagonists. Yet, as drafted, there is no direct nexus between the claimed outcome and method of treating. See MPEP 1112.02. It would be remedial to amend claim 8 to include terminology such as "in need thereof" when describing the mammal to be treated such that the claim establishes a clear nexus between the outcome and method of treating. See *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003). Currently, the preamble is not afforded patentable weight and claim 8 is thus read to recite only the method comprising administering to a mammal a compound represented by formula (II) in a pharmaceutically effective amount.

14. *Tada et al* disclose the compound represented by formula (II) in the instant application (abstract). Furthermore, *Tada et al* teach "a method... which comprises administering to the mammal a pharmaceutically effective amount" of the compound

(Column 363, Lines 49-51). Accordingly, *Tada et al* anticipate each element of claim 8 as claimed.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. **Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tada et al (US 6,977,266) in view of** *Berdyshev et al* (Life Sci 63(8):PL125-129, 1998)

17. As discussed above, instant claim 8 is vague and indefinite. Moreover, as also discussed above, instant claim 8 does not provide a direct nexus between the claimed outcome and the method of treating. In the alternative, however, the preamble of claim 8 may be given weight. As discussed above, *Tada et al* disclose the compound represented by formula (II) in the instant application (abstract), which is a CB2 agonist. Furthermore, *Tada et al* teach "a method... which comprises administering to the mammal a pharmaceutically effective amount" of the compound (Column 363, Lines 49-51). *Tada et al* also teach "the compound of the present invention can be used for treating or preventing diseases related to the canabinoid type 2 receptor" (Column 60, Lines 55-57) and, more specifically, "the present compounds can be used as anti-inflammatory agents, anti-allergenic agents, analgesic agents, immunodeficiency treating agents, autoimmune disease treating agents, chronic rheumatoid arthritis treating agents, multiple sclerosis treating agents, encephaloma treating agents,

glaucoma treating agents or the like" (Column 61, Lines 3-14). However, *Tada et al* do not specifically teach the use of the compound for treating the respiratory conditions recited by instant claim 8.

18. *Berdyshev et al* teach the use of cannabinoid type 2 receptor agonists to treat the pathological effects encompassed by instant claim 8. Specifically, *Berdyshev et al* tested the effects of cannabinoid receptor agonists on bronchopulmonary inflammation in mice and found that the CB2 agonist, WIN 55,212,2, reduced the recruitment neutrophils (inflammatory cells) and downmodulated bronchopulmonary inflammation (a pathological effect of an inflammatory cell infiltration in the respiratory tract and a hyperirritability of the respiratory tract) (Page PL-128).

19. Since *Tada et al* teach the use of the instant compound represented by the formula (II), which is a CB2 agonist, in the treatment of diseases, and since *Berdyshev et al* teach that CB2 agonists "inhibited LPS-induced pulmonary inflammation and suggest that this effect could be at least in part mediated by the cannabinoid CB2 receptor" (abstract), it would have been prima facie obvious to a person of ordinary skill in the art to use the CB2 agonist as taught by *Tada et al* to treat an inflammatory cell infiltration or respiratory hyperirritability as taught by *Berdyshev et al*. Accordingly, claim 8 is obvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571)270-

5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CRAIG RICCI/
Examiner, Art Unit 4161

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4161